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Elsevier gratefully acknowledges the opportunity to contribute to the NIH meeting on Public Access and the opportunity to contribute to the NIH's Public Access Policy Request for Information.

Elsevier has an unqualified commitment to encouraging wide access to authoritative, peer-reviewed scientific, technical and medical research and continually tests new approaches to access and dissemination of research to meet the evolving needs of the diverse communities we serve.

Due to the far-reaching implications of the NIH's new Public Access Policy on grantees, authors, institutions and publishers, we urge the NIH to expand its consultative process and conduct a Notice and Comment Rulemaking as defined by the Administrative Procedures Act. We believe the public should be given an opportunity to comment on the new policy before it goes into effect. Indeed, in 2005, when the NIH introduced the voluntary Public Access Policy, the NIH stated: "We believe that the voluntary nature of the final policy is preferable to a 'one size fits all' requirement, as it permits sufficient flexibility to accommodate the needs of different stakeholders." The significant departure from this position warrants a formal consultation with stakeholders. HHS should follow the Administrative Procedures Act and stay the effective date of the mandate until a full Notice and Comment Rulemaking is completed.

We urge the NIH to ensure that the implementation of the policy will respect the basic principles embodied in copyright and not undermine those rights that provide incentives for publishers to invest in peer-review, publishing and the communication of scientific and medical research. Without sufficient consideration the mandatory Public Access Policy could have unintended and undesirable consequences.

Rulemaking will ensure critical questions are addressed:


- A. PubMed Central (PMC) content overlaps with publisher content and PMC may compete with publisher websites. How will the NIH ensure that content on PMC will not displace the definitive published version, and what actions are the NIH undertaking to ensure that PMC does not undermine the viability of journals whose economic stability varies widely?
- B. Will the NIH share bibliographic usage information so that publishers can quantify the degree to which PMC is competing with publisher websites and resulting in loss of publisher website traffic?
- C. Revenue sources for publishers, including subscriptions, 'one-off' transactional sales, commercial redistribution rights, and online ad or classified display could be compromised threatening a publisher's ability to cover costs or make new investments. How will the NIH ensure the policy will not negatively impact commercial, nonprofit and society publishers and will the NIH compensate publishers for the added-value of services that publishers provide?

- D. Many manuscripts currently appear on PMC in contravention to publisher policies. How will the NIH ensure individuals post the correct manuscript version to PMC to be publicly available at the correct time, as consistent with publisher policies?
- E. Third parties could commercially exploit content that appears on PMC without the consent of the publisher. How will the NIH prevent copyrighted material available on PMC from being altered, pirated, made into derivative works, redisplayed, republished and resold?
- F. In the NIH's processing of manuscripts, manuscripts that appear on PMC may differ from the definitive version hosted by the publisher. How will the NIH ensure that researchers are not misled as to the accuracy and validity of manuscripts on PMC?

For the past three years, Elsevier has sought to work collaboratively with the NIH in its implementation of the voluntary Public Access Policy. Elsevier has proactively identified authors who report NIH-funded research, deposited their manuscripts to PMC and actively monitored policy compliance. However, we consider the change to a mandatory policy a very significant step. It should not be done hastily. There is a fundamental difference between the government working with researchers and the publishing community to achieve common goals, and the government asserting rights to copyrighted content.

In conclusion, we see STM publishing as a system that has developed over many years and is core to the continuing success of the research community. We are keen to sustain quality and balance in its continuing evolution. We wish to work collaboratively with all key players, particularly the NIH, to demonstrate leadership in optimizing this evolution, to address the issues we raise and to develop viable solutions that will benefit everyone. A rulemaking is an important and necessary step to continue to optimize this evolution.

Sincerely,



James Phimister, Ph.D.
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